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Re-evaluation Note

REV2009-05

Proposed Risk Mitigation Measures for Eight Rodenticides

(publié aussi en français)

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Executive Summary

The purpose of this document is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) is proposing additional risk mitigation measures for eight rodenticides (brodifacoum, bromadiolone, bromethalin, chlorophacinone, difethialone, diphacinone, warfarin and zinc phosphide) as part of an overall risk-reduction strategy for rodenticides in Canada. Furthermore, these measures may be applied to new active ingredients when risk mitigation measures are required. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications.

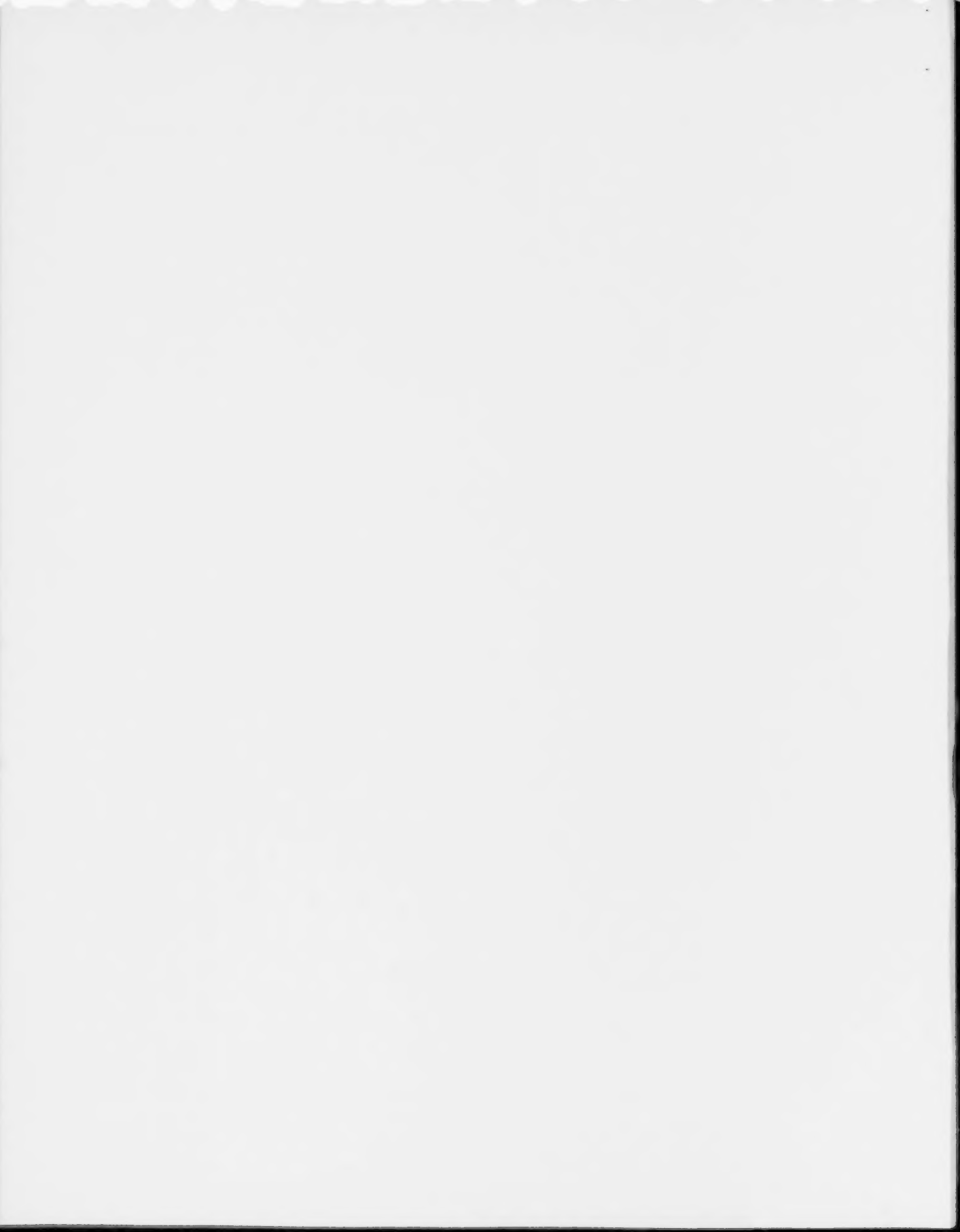


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1.0 Background

In Re-evaluation Decision Document RRD2006-11, *Brodifacoum, Bromadiolone, Chlorophacinone, Diphacinone and Warfarin*, and Re-evaluation Decision RVD2007-01, *Zinc Phosphide*, published in 2006 and 2007, respectively, the PMRA required label advisory statements to protect children, non-target animals and handlers. The PMRA also required that baits must be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock. The PMRA also required that the labels of commercial class end-use products be amended to state these products were to be used only by certified pest control operators, farmers and persons authorized in government-approved pest control programs as well as to include additional personal protective equipment (PPE).

In March 2007, the PMRA announced, through the Re-evaluation Note REV2007-04, *Update on the Re-evaluation of Rodenticides*, that it was considering requiring additional risk mitigation measures, similar to those proposed by the USEPA in their *Proposed Risk Mitigation Decision for Nine Rodenticides* (2007). The PMRA invited the public to provide comments on the 2007 Re-evaluation Note. The comments received have also been taken into consideration in the current document.

This document proposes additional protective measures to further protect children, pets and non-target wildlife from the risks associated with the use of eight rodenticides in Canada, similar to the regulatory actions finalized by the USEPA in *Risk Mitigation Decision for Ten Rodenticides* in 2008. These additional measures apply to the rodenticides the PMRA re-evaluated in 2006 and 2007—warfarin, chlorophacinone, diphacinone, brodifacoum, bromadiolone and zinc phosphide—as well as two others that were not subject to re-evaluation—difethialone and bromethalin. The PMRA invites and encourages the public and all interested parties to provide written comments on these proposed risk mitigation measures.

2.0 Chemicals Subject to the Proposed Risk Mitigation Measures

The eight rodenticides that are the subject of this document can be divided into the following categories:

- non-anticoagulants: bromethalin and zinc phosphide;
- first-generation anticoagulants: warfarin, chlorophacinone and diphacinone; and
- second-generation anticoagulants: brodifacoum, bromadiolone and difethialone.

3.0 Description of Registered Canadian Uses

In Canada, these rodenticides are currently registered for use in a variety of use sites, including in and around residential, agricultural, commercial, industrial and public buildings. Some of the active ingredients are also registered for outdoor use sites such as sewers, garbage dumps, fields, nurseries, and rangelands. A detailed summary of the registered uses for each of the eight rodenticides is shown in Appendix I.

3.1 Formulation Types

The domestic class rodenticide products that are registered are formulated as a solid bait (i.e. meal bait, pellets, ready-to-use place packs, paraffin blocks), except for one. This product is formulated as a liquid concentrate that requires dilution in water before use. Currently, five domestic class products are sold pre-packaged in bait stations.

The majority of the commercial class rodenticide products registered in Canada are formulated as a solid bait (i.e. meal bait, pellets, ready-to-use place packs, paraffin blocks). Commercial class products can also be formulated as liquid or powder concentrates that must be mixed with suitable bait material. The one restricted end-use product registered in Canada is formulated as a tracking powder.

4.0 Summary of the Risks

The measures the USEPA required in 2008 are based on concerns regarding reported exposure of children to rodenticides and risks to non-target wildlife.

4.1 Risk to Children

Since 1993, the American Association of Poison Control Centers has received reports annually of approximately 12 000 to 15 000 rodenticide exposures in children younger than 6 years old. For the years 1999 through 2003, an average of 115 cases of exposure per year were symptomatic, an average of 3617 cases per year were treated in a health care facility and an average of 17 cases per year required treatment in an intensive care unit. Based on this, the USEPA has concluded that the number of exposure incidents resulting in symptomatic diagnoses and/or requiring treatment was unacceptably high given that feasible measures for reducing exposure are available. The USEPA also believed that the number of non-symptomatic exposure incidents was unacceptably high because of the social cost associated with evaluating and treating children who might have been exposed.

4.2 Ecological Risk

The risks to pets and wildlife are from primary exposure (direct consumption of rodenticide bait) for all compounds and from secondary exposure (consumption by predators or scavengers of prey with rodenticide stored in body tissues) to the anticoagulants. Secondary exposure to the second-generation anticoagulants is particularly problematic due to these compounds' high toxicity and long persistence in the body. The second-generation anticoagulants are designed to be toxic in a single dose. But given the time to death is about five to seven days, the target rodent can feed multiple times before death, leading to a carcass containing residues that may be many times the lethal dose. In addition, the extended persistence of second-generation anticoagulants in the body of a predator or scavenger can result in adverse effects from additive exposures through multiple feedings that are separated by days or weeks.

The USEPA evaluated multiple lines of evidence for their comparative ecological risk assessment and concluded that the second-generation anticoagulants have a greater potential to affect non-target wildlife adversely, especially birds, than the first-generation anticoagulants.

4.3 Assessment of Exposure and Risks in Canada

As of 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

Given this requirement has only been in effect since 2007, the PMRA considers the available information regarding incidents related to the use of rodenticides in Canada is still insufficient to assess the exposure of children and non-target wildlife to these products. The PMRA considers the USEPA's observations and assessments as being representative of what could be expected to be observed in Canada and, therefore, concurs with the risks identified in the USEPA's decision document.

Furthermore, in its risk assessments for zinc phosphide and the rodenticide cluster, the PMRA identified various levels of risk to non-target terrestrial organisms from primary and secondary exposure to rodenticides. Brodifacoum in particular was identified as the rodenticide that possesses the highest risk to non-target birds and mammals. In RRD2006-11, the PMRA required that the use of products containing brodifacoum be restricted to indoors only. Difethialone, a second generation rodenticide, has properties that are very similar to brodifacoum (chemical structure, toxicity and persistence). Difethialone was not included in the rodenticide re-evaluation (RRD2006-11) because it was registered recently in Canada (March 2000). Given the similarity of difethialone and brodifacoum and the similarity of the risks both pose to non-target animals, the PMRA is proposing that any mitigation measures required for brodifacoum be applied to difethialone.

5.0 Proposed Canadian Regulatory Actions

5.1 Proposed Mitigation Measures Pertaining to Risks to Children and Pets

To reduce the risk of exposure of children and pets to rodenticides, the PMRA is proposing the following risk mitigation measures.

- Domestic class rodenticide bait products must be sold packaged with a ready-to-use (prebaited) bait station. The level of tamper-resistance required varies depending on the intended use site (see Section 6.2).
- Bait stations packaged with domestic class products may be non-refillable (disposable, one-time-use stations) or refillable (sold with bait refills). Bait refills may not be sold individually; they must be sold with at least one bait station.
- For domestic class products, loose bait forms (i.e. meal, treated whole grain, pelleted and liquid, whether packaged in placepacks or not) are prohibited.

The domestic class products registered solely for use outdoors and applied below-ground for controlling certain pests (for example, ground squirrels) are exempt from the requirement for bait stations and the prohibition on pelleted, meal and treated whole-grain forms of bait. This exemption results from the fact that below-ground baits must be put directly into the underground burrow systems; therefore, bait stations would affect the efficacy of the products. In the case of domestic class products that are currently labelled for below-ground use against certain pests and above-ground use against other pests, the registrant would need either to cancel the above-ground uses or to comply with the requirements for bait stations and solid bait forms. The acceptability for registration of new bait products that are to be used outdoors and applied below-ground (in terms of human and ecological risk) will be determined on a case-by-case basis.

5.2 Proposed Regulatory Action Relating to Ecological Risks

To reduce the risks to wildlife from exposure to rodenticides, the PMRA is proposing the following risk mitigation measures.

- Brodifacoum, bromadiolone and difethialone (second-generation anticoagulants) domestic class products are prohibited.
- All outdoor uses of brodifacoum and difethialone are prohibited.
- The labels of end-use products that allow rat and mouse baits to be placed "in and around buildings", "indoors and against the outside walls of buildings" or "inside and in areas adjacent to buildings" must be amended to read "indoors and outdoors against the outside walls of buildings." This restriction applies to placing rat and mouse baits around residential, commercial, agricultural (for example, feed barns, storage sheds, poultry houses), industrial and public buildings as well as closed structures, including garbage dumpsters and transport/cargo vehicles. This restriction does not apply to other outdoor uses, including rangeland, fields, nurseries, orchards, shelter belts, plantations and cropland.
- All outdoor, above-ground placements of bait products must be contained in bait stations. Tamper-resistant (tier 1) bait stations¹ are required if the bait placement is within reach of pets, domestic animals, non-target wildlife or children under six years of age. Other types of bait stations may be constructed and used in settings, such as around livestock production buildings, where exposure of children and non-target wildlife is unlikely.
- Commercial class, liquid products containing brodifacoum, bromadiolone or difethialone (second-generation anticoagulants) are prohibited.

¹ See Sections 6.2 and 6.3.

5.3 Proposed Regulatory Action Relating to Exposure Risks for Handlers, Children, Pets and Wildlife

- The labels of commercial class products formulated as meal, treated whole-grain or pellets must be amended to prohibit use where children, domestic animals or non-target wildlife may be exposed.
- The labels of commercial class products must be amended to state that bait stations are required where exposure to children, pets, livestock or non-target wildlife is possible.
- The outdoor use or use in residential settings of commercial class, concentrated products (i.e. solution, emulsifiable concentrate, dust, powder) to be diluted into solid or liquid bait is prohibited.
- The labels of commercial class products containing bromethalin and difethialone must be amended to state these products are only to be used certified operators, farmers and persons authorized in government-approved pest control programs.²
- The applicable label amendments (first aid, storage, precautions) required for warfarin, brodifacoum, bromadiolone, diphacinone and chlorophacinone in RRD2006-11 and for zinc phosphide are now also required for difethialone and bromethalin in RRD2007-01.

The standards regarding the bait stations (required in the zinc phosphide and rodenticide cluster re-evaluation decision documents) must be modified to reflect the new requirements for bait stations. Canadian requirements for bait stations are described in Sections 6.2 and 6.3 of this document.

A summary of the proposed mitigation measures is presented in Appendix II for domestic class products and in Appendix III for commercial class products. The proposed labelling requirements are detailed in Appendix IV for domestic class products and Appendix V for commercial class end-use products.

6.0 Implementation of the Regulatory Action

6.1 Proposed Timeline for Implementation

6.1.1 A 90-Day Response Regarding Intent to Comply

Registrants must send a letter to the PMRA within 90 days of finalization of this regulatory decision declaring they intend to comply or not to comply with the risk mitigation decision for each of their registered rodenticide products. Should registrants intend to not comply, they must notify the PMRA they intent to discontinue sales of these products. The PMRA will take into

² This requirement was published for chlorophacinone, diphacinone and warfarin in RVD2006-11 and for zinc phosphide in RRD2007-01; this is now also required for bromethalin and difethialone.

consideration the last date of sale of products proposed by the registrants when processing discontinuation.

6.1.2 Submission for Amendments Consistent with the Risk Mitigation Decision

For products for which registrants intend to comply as outlined in their response, registrants must submit an application to amend the product labels and/or package within 18 months of finalization of the risk mitigation decision.

6.2 Ready-to-Use Bait Stations

The PMRA is proposing that domestic class products be sold packaged with ready-to-use (prebaited) tamper-resistant bait stations. With regards to the level of tamper-resistance of the bait stations, the PMRA is proposing to adopt the same criteria as those the USEPA specified.

- The bait stations may be non-refillable (disposable, one-time-use stations) or refillable (sold with bait refills). The tier 1 to 4 designations are indicators of the resistance of packaging:
 - **Tier 1** bait stations are tamper-resistant for children and dogs, and are weather resistant. They can be used both indoors and outdoors.
 - **Tier 2** bait stations are tamper-resistant for children and dogs. They can only be used indoors.
 - **Tier 3** bait stations are tamper-resistant for children only. They can only be used indoors, in locations inaccessible to pets, domestic animals or non-target wildlife.
 - **Tier 4** bait stations are non-refillable (one-time use only). They can only be used indoors, in locations inaccessible to children, pets, domestic animals or non-target wildlife. These bait stations are self-certified by the registrants. Please note that the registrants must certify that the bait station is made of a material of sufficient rigidity such that the station is not easily crushed or opened by children younger than 6 years old, not easily chewed by rats/mice and not reasonably anticipated to release rodenticide bait except for bait removed by target rodents and minor quantities of crumbs created by target rodents.
- To be sold with domestic class end-use products in Canada, Registrants will need to test Tier 1, 2 and 3 bait stations for tamper-resistance according to USEPA protocols.³
- For domestic class products sold with tier 4 bait stations, a self-certification statement about packaging must be provided to the PMRA.

³ These protocols are provided in the USEPA's *Risk Mitigation Decision for Ten Rodenticides*.

- The labels of domestic class end-use products must indicate if the bait station included in the packaging can be used indoors and outdoors (i.e. tier 1) or indoors only (tier 2, 3 and 4) and must indicate the bait station's ability to isolate bait from children and/or pets.
- Bait stations for mouse control are required to accommodate bait placements of between 7 and 28 g of bait. Bait stations for rat control are required to accommodate bait placements of between 113 and 454 g of bait for warfarin, diphacinone or chlorophacinone baits; between 28 and 170 g of bait for bromethalin baits; and between 4 and 9 g of bait for zinc phosphide.

6.3 Bait Stations Sold Without Bait

Bait stations that are sold without bait are considered to be application equipment. Therefore, they are not pest control products and not regulated directly by the *Pest Control Products Act*. However, rodenticide products registered in Canada must be used in bait stations in certain situations. In such cases, the users of rodenticide baits are responsible for obtaining or constructing bait stations that are appropriate for the use situation (i.e. resistant to weather, to tampering by children and dogs) and consistent with label requirements. Please refer to Appendix VI, Requirements for Bait Stations Used for the Placement of Rodenticide Bait,⁴ for more information regarding these requirements. These requirements will be published as an Information Note upon finalization of this regulatory decision.

7.0 Supporting Documentation

The PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on Health Canada's website at healthcanada.gc.ca/pmra. The PMRA documents are also available through the Pest Management Information Service.

The USEPA's *Risk Mitigation Decision for Ten Rodenticides* and the *Proposed Risk Mitigation Document for Nine Rodenticides* are available at www.regulations.gov.

⁴

A proposed version of the Information Note *Requirements for Bait Stations Used for the Placement of Commercial Class Rodenticide Bait Products* is shown in Appendix VI.

Appendix I Registered Uses of Bromethalin, Zinc Phosphide, Warfarin, Chlorophacinone, Diphacinone, Brodifacoum, Bromadiolone and Difethialone in Canada

Use(s)	Non-Anticoagulants		First-Generation Anticoagulants			Second-Generation Anticoagulants		
	Bromethalin	Zinc Phosphide	Warfarin	Chlorophacinone	Diphacinone	Brodifacoum	Bromadiolone	Difethialone ¹
In and around agricultural buildings (non-feed and food)	✓	✓	✓	✓	✓	✓ (indoor use only)	✓	✓
In and around processing plants (feed and food in non-food areas)	✓		✓	✓	✓	✓ (indoor use only)		✓
Meat and food manufacturing areas	✓			✓				✓
In and around food service establishments (non-food areas)	✓		✓	✓	✓	✓ (indoor use only)		✓
In and around residential buildings	✓	✓	✓	✓	✓	✓ (indoor use only)	✓	✓
In and around industrial buildings	✓	✓		✓	✓		✓	✓
In and around commercial buildings				✓				✓
In and around public buildings				✓				✓
Granary bins (empty)			✓	✓	✓	✓ (indoor use only)		
Storage areas (non-food)		✓	✓	✓	✓	✓ (indoor use only)		
Garbage dumps				✓	✓			
Sewers				✓	✓			✓

Appendix I Registered Uses of Bromethalin, Zinc Phosphide, Warfarin, Chlorophacinone, Diphacinone, Brodifacoum, Bromadiolone and Difethialone in Canada

Use(s)	Non-Anticoagulants		First-Generation Anticoagulants			Second-Generation Anticoagulants		
	Bromethalin	Zinc Phosphide	Warfarin	Chlorophacinone	Diphacinone	Brodifacoum	Bromadiolone	Difethialone ¹
In and around agricultural buildings (non-feed and food)	✓	✓	✓	✓	✓	✓ (indoor use only)	✓	✓
In and around processing plants (feed and food in non-food areas)	✓		✓	✓	✓	✓ (indoor use only)		✓
Meat and food manufacturing areas	✓			✓				✓
In and around food service establishments (non-food areas)	✓		✓	✓	✓	✓ (indoor use only)		✓
In and around residential buildings	✓	✓	✓	✓	✓	✓ (indoor use only)	✓	✓
In and around industrial buildings	✓	✓		✓	✓		✓	✓
In and around commercial buildings				✓				✓
In and around public buildings				✓				✓
Granary bins (empty)			✓	✓	✓	✓ (indoor use only)		
Storage areas (non-food)		✓	✓	✓	✓	✓ (indoor use only)		
Garbage dumps				✓	✓			
Sewers				✓	✓			✓

Use(s)	Non-Anticoagulants		First-Generation Anticoagulants			Second-Generation Anticoagulants		
	Bromethalin	Zinc Phosphide	Warfarin	Chlorophacinone	Diphacinone	Brodifacoum	Bromadiolone	Difethialone ¹
Transport vehicles								
Rangeland		✓		✓	✓			
Non-crop areas		✓		✓	✓			
Cropland				✓	✓			
Orchards		✓		✓	✓			
Nurseries and ornamentals		✓		✓	✓			
Farm yards					✓			
Grain fields					✓			
Alfalfa fields, hay fields		✓						
Pastures		✓						
Golf course, parks		✓						
Turf					✓			
Vegetable gardens					✓			
Christmas tree plantations /newly reforested areas/ shelterbelts		✓			✓			
Wet and damp locations (river banks, railroad tracks, loading areas, landfill)					✓			
Along fences					✓			

¹ In this consultation document, the use of difethialone will be restricted to indoors only (see Appendix V).

Appendix II Summary of the Proposed Risk Mitigation Measures for Domestic Class Products Containing Brodifacoum, Bromadiolone, Bromethalin, Chlorophacinone, Difethialone, Diphacinone, Warfarin or Zinc Phosphide

Marketing Class	Proposed Risk Mitigation Measures	
Domestic	Applicator	Anyone
	Bait form	Block or solid form only. Loose bait forms (i.e. meal, treated whole-grain, pelleted and liquid) are prohibited.
	Packaging	<ul style="list-style-type: none"> • Products must be sold packaged with a ready-to use (prebaited) bait station meeting the requirements of Tier 1, 2, 3 or 4 (see Section 6.2). • Bait stations for mouse control are required to accommodate bait placements of between 7 and 28 g of bait. Bait stations for rat control are required to accommodate bait placements of between 113 and 454 g of bait for warfarin, diphacinone, or chlorophacinone baits; between 28 and 170 g of bait for bromethalin baits; and between 4 and 9 g of bait for zinc phosphide. • Bait stations packaged with domestic class products may be non-refillable (disposable, one-time-use stations) or refillable (sold with bait refills). Bait refills may not be sold individually; they must be sold with at least one bait station.
	Label amendments ¹ / mitigation measures	<ul style="list-style-type: none"> • Labels of domestic class products must be amended to read "Bait MUST be placed in tamper-resistant bait stations." • Labels of end-use products that allow rat and mouse baits to be placed "in and around buildings", "indoors and against the outside walls of buildings" or "inside and in areas adjacent to buildings" need to be amended to read "indoors and outdoors against the outside walls of buildings." • The labels of Domestic class end-use products must indicate if the bait station included in the packaging can be used indoors and outdoors (i.e. tier 1) or indoors only (tier 2, 3 and 4) and indicate the bait station's ability to isolate bait from children, and/or pets. • Domestic class products containing second-generation anticoagulants (i.e. brodifacoum, bromadiolone and difethialone) are prohibited.

¹ The proposed labelling requirements are detailed in Appendix IV.

Use(s)	Non-Anticoagulants		First-Generation Anticoagulants			Second-Generation Anticoagulants		
	Bromethalin	Zinc Phosphide	Warfarin	Chlorophacinone	Diphacinone	Brodifacoum	Bromadiolone	Difethialone ¹
Transport vehicles								
Rangeland		✓		✓	✓			
Non-crop areas		✓		✓	✓			
Cropland				✓	✓			
Orchards		✓		✓	✓			
Nurseries and ornamentals		✓		✓	✓			
Farm yards					✓			
Grain fields					✓			
Alfalfa fields, hay fields		✓						
Pastures		✓						
Golf course, parks		✓						
Turf					✓			
Vegetable gardens					✓			
Christmas tree plantations /newly reforested areas/ shelterbelts		✓			✓			
Wet and damp locations (river banks, railroad tracks, loading areas, landfill)					✓			
Along fences					✓			

¹ In this consultation document, the use of difethialone will be restricted to indoors only (see Appendix V).

Appendix II

**Summary of the Proposed Risk Mitigation Measures for
Domestic Class Products Containing Brodifacoum,
Bromadiolone, Bromethalin, Chlorophacinone,
Difethialone, Diphacinone, Warfarin or Zinc Phosphide**

Marketing Class	Proposed Risk Mitigation Measures	
Domestic	Applicator	Anyone
	Bait form	Block or solid form only. Loose bait forms (i.e. meal, treated whole-grain, pelleted and liquid) are prohibited.
	Packaging	<ul style="list-style-type: none"> • Products must be sold packaged with a ready-to use (prebaited) bait station meeting the requirements of Tier 1, 2, 3 or 4 (see Section 6.2). • Bait stations for mouse control are required to accommodate bait placements of between 7 and 28 g of bait. Bait stations for rat control are required to accommodate bait placements of between 113 and 454 g of bait for warfarin, diphacinone, or chlorophacinone baits; between 28 and 170 g of bait for bromethalin baits; and between 4 and 9 g of bait for zinc phosphide. • Bait stations packaged with domestic class products may be non-refillable (disposable, one-time-use stations) or refillable (sold with bait refills). Bait refills may not be sold individually; they must be sold with at least one bait station.
	Label amendments ¹ / mitigation measures	<ul style="list-style-type: none"> • Labels of domestic class products must be amended to read "Bait MUST be placed in tamper-resistant bait stations." • Labels of end-use products that allow rat and mouse baits to be placed "in and around buildings", "indoors and against the outside walls of buildings" or "inside and in areas adjacent to buildings" need to be amended to read "indoors and outdoors against the outside walls of buildings." • The labels of Domestic class end-use products must indicate if the bait station included in the packaging can be used indoors and outdoors (i.e. tier 1) or indoors only (tier 2, 3 and 4) and indicate the bait station's ability to isolate bait from children, and/or pets. • Domestic class products containing second-generation anticoagulants (i.e. brodifacoum, bromadiolone and difethialone) are prohibited.

The proposed labelling requirements are detailed in Appendix IV.

Appendix III Summary of the Proposed Risk Mitigation Measures for Commercial Class Products Containing Brodifacoum, Bromadiolone, Bromethalin, Chlorophacinone, Difethialone, Diphacinone, Warfarin or Zinc Phosphide

Marketing Class	Proposed Risk Mitigation Measures	
Commercial	Applicator	Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.
	Bait form	All bait forms all allowed, with the exception of liquid for products containing brodifacoum, bromadiolone or difethialone (second-generation anticoagulants).
	Packaging	Commercial class products are not required to be sold packaged with bait stations.
	Label amendments ¹ / mitigation measures	<ul style="list-style-type: none"> Labels of products must be amended to read "Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets, livestock or non-target wildlife." Labels of end-use products that allow rat and mouse baits to be placed "in and around buildings", "indoors and against the outside walls of buildings" or "inside and in areas adjacent to buildings" must be amended to read "indoors and outdoors against the outside walls of buildings." All outdoor, above-ground placements of bait products must be contained in bait stations. Tamper-resistant bait stations are required if the bait placement is within reach of pets, domestic animals, non-target wildlife, or children under six years-of-age. The placement of meal, treated whole-grain or pelleted form of bait is prohibited where children, domestic animals or non-target wildlife may be exposed. The outdoor use or use in residential settings of commercial class, concentrated products (i.e. solution, emulsifiable concentrate, dust, powder) to be diluted into solid or liquid bait is prohibited. The labels of commercial class products must be amended to reflect the new requirements for bait stations used for the placement of commercial class bait products. The use of difethialone is restricted to indoor use only. Labels of bromethalin and difethialone commercial class products must be amended to include additional precautions/first aid/storage label statements.

¹ The proposed labelling requirements are detailed in Appendix V.

Appendix III Summary of the Proposed Risk Mitigation Measures for Commercial Class Products Containing Brodifacoum, Bromadiolone, Bromethalin, Chlorophacinone, Difethialone, Diphacinone, Warfarin or Zinc Phosphide

Marketing Class	Proposed Risk Mitigation Measures	
Commercial	Applicator	Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.
	Bait form	All bait forms all allowed, with the exception of liquid for products containing brodifacoum, bromadiolone or difethialone (second-generation anticoagulants).
	Packaging	Commercial class products are not required to be sold packaged with bait stations.
	Label amendments ¹ / mitigation measures	<ul style="list-style-type: none"> • Labels of products must be amended to read "Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets, livestock or non-target wildlife." • Labels of end-use products that allow rat and mouse baits to be placed "in and around buildings", "indoors and against the outside walls of buildings" or "inside and in areas adjacent to buildings" must be amended to read "indoors and outdoors against the outside walls of buildings." • All outdoor, above-ground placements of bait products must be contained in bait stations. Tamper-resistant bait stations are required if the bait placement is within reach of pets, domestic animals, non-target wildlife, or children under six years-of-age. • The placement of meal, treated whole-grain or pelleted form of bait is prohibited where children, domestic animals or non-target wildlife may be exposed. • The outdoor use or use in residential settings of commercial class, concentrated products (i.e. solution, emulsifiable concentrate, dust, powder) to be diluted into solid or liquid bait is prohibited. • The labels of commercial class products must be amended to reflect the new requirements for bait stations used for the placement of commercial class bait products. • The use of difethialone is restricted to indoor use only. • Labels of bromethalin and difethialone commercial class products must be amended to include additional precautions/first aid/storage label statements.

¹ The proposed labelling requirements are detailed in Appendix V.

Appendix IV Canadian Labelling Requirements for Domestic Class End-Use Products

NOTE: The information in this appendix summarizes required label statements for domestic class products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin. This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary personal protective equipment (PPE) that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

The labels of all domestic class products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin must be amended as follows.

- In the **USE LIMITATIONS** section, the following statement must be removed:

Bait **MUST** either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock.

and must be replaced with the following:

Bait **MUST** be placed in tamper-resistant bait stations.

The labels of domestic class end-use products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin packaged with tier 1 bait stations must be modified to include:

- On the front panel,

This bait station is resistant to weather and to tampering by children and pets. For use indoors and outdoors.

- In the **USE LIMITATIONS** section,

This bait station may be used indoors and outdoors against the walls of buildings accessible to children, pets and non-target animals, consistent with all use restrictions and other requirements indicated on this label.

The labels of domestic class end-use products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin packaged with tier 2 bait stations must be modified to include:

- On the front panel,

This bait station is resistant to tampering by children and pets. Use indoors only.

- In the **USE LIMITATIONS** section,

This bait station may be used in indoor areas accessible to children and pets, consistent with all use restrictions and other requirements indicated on this label. **DO NOT USE THIS PRODUCT OUTDOORS.**

The labels of domestic class end-use products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin packaged with tier 3 bait stations must be modified to include:

- On the front panel,

This bait station is resistant to tampering by children. Use indoors only.

- In the **USE LIMITATIONS** section,

This bait station may be used in indoor areas accessible to children, consistent with all use restrictions and other requirements indicated on this label. **DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO PETS, DOMESTIC ANIMALS, OR NON-TARGET WILDLIFE.**

The labels of domestic class end-use products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin packaged with tier 4 bait stations must be modified to include:

- On the front panel,

This bait station is not tamper-resistant. Use indoors only in areas inaccessible to children and pets.

- In the **USE LIMITATIONS** section,

DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO CHILDREN, PETS, DOMESTIC ANIMALS, OR NON-TARGET WILDLIFE.

The labels of domestic class end-use products containing warfarin, diphacinone, zinc phosphide, chlorophacinone or bromethalin that currently allow rat and mouse baits to be placed “in and around buildings”, “indoors and against the outside walls of buildings” or “inside and in areas adjacent to buildings” must be amended to read:

indoors and outdoors against the outside walls of buildings.

This restriction applies to placing rat and mouse baits around residential, commercial and public buildings as well as closed structures, including garbage dumpsters. This restriction does not apply to other outdoor uses.

Appendix V Canadian Labelling Requirements for Commercial Class End-Use Products

NOTE: The information in this appendix summarizes required label statements for commercial class products containing warfarin, brodifacoum, bromadiolone, diphacinone, zinc phosphide, chlorophacinone, difethialone or bromethalin. This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary personal protective equipment (PPE) that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

To ensure that the use of commercial class end-use products is limited to certified pest control operators, farmers and persons authorized in government-approved pest control programs, the labels of commercial class products containing bromethalin or difethialone must be modified to include the following statement:

- On the principal panel of the label,

 Only to be used by certified pest control operators, farmers and persons
 authorized in government-approved pest control programs.

The labels of all commercial end-use product containing bromethalin or difethialone, with the exception of those products that are packaged in pre-measured place packs (i.e. place pack must not be opened), must be modified to include the following statements:

- In the **PRECAUTIONS** section of the label,

 KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK.
 May be harmful or fatal if swallowed or absorbed through the skin.
 Chemical-resistant gloves must be worn when handling product and when
 disposing of dead rodents, unconsumed bait and empty containers. Avoid
 contact with eyes, skin or clothing. Wash hands before eating, drinking,
 chewing gum, using tobacco or using the toilet. Wash skin thoroughly
 with soap and water after handling. Wash contaminated clothing,
 separately from other laundry, with soap and hot water before reuse.
 KEEP AWAY FROM FEED AND FOODSTUFFS.

The end-use product labels of commercial pre-measured place packs (i.e. place pack must not be opened) containing bromethalin or difethialone must be modified to include the following statements:

- In the **PRECAUTIONS** section of the label,

KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK.
May be harmful or fatal if swallowed or absorbed through the skin. Do not open pre-measured place packs. Chemical-resistant gloves must be worn when disposing of dead rodents, unconsumed bait and empty containers. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Wash skin thoroughly with soap and water after handling. Wash contaminated clothing, separately from other laundry, with soap and hot water before reuse. KEEP AWAY FROM FEED AND FOODSTUFFS.

The end-use product labels of commercial class products containing bromethalin or difethialone must be amended to include:

- In the **FIRST AID** section of the label,

For all cases of human ingestion, immediately notify a physician or poison control centre.

If pet or livestock poisoning is suspected, immediately contact a veterinarian.

- In the **STORAGE** section of the label,

Store in a cool, dry place away from other chemicals and food or feed.
Store product not in use, in original container, in a secure location inaccessible to children and non-target animals.

- In the **DIRECTIONS FOR USE** section,

Users should remove clothing immediately if pesticide gets inside. Then wash skin thoroughly and put on clean clothing.

For commercial pellet and bait formulations containing bromethalin or difethialone not already packaged in place packs, the following statement is required on all end-use product labels:

- In the **PRECAUTIONS** section,

All handlers must wear long-sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves when handling this product.

Commercial class end-use product labels of products containing warfarin, brodifacoum, bromadiolone, diphacinone, zinc phosphide, chlorophacinone, difethialone or bromethalin must be amended as follows:

- In the **USE LIMITATIONS** section of those labels of products that consist of meal, treated whole-grain and pelleted forms of bait, the following statement must be removed:

Bait **MUST** either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock.

and must be replaced with the following:

Do **NOT** use in locations where children, domestic animals, or non-target wildlife may be exposed.

- In the **USE LIMITATIONS** section of the product labels, with the exception of those products that consist of meal, treated whole-grain and pelleted forms of bait, the following statement must be removed:

Bait **MUST** either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock.

and must be replaced with the following:

Bait **MUST** be placed either in tamper-resistant bait stations or in locations not accessible to children, pets, livestock or non-target wildlife.

- In the **USE LIMITATIONS** section, the following statement must be removed:

To ensure safe use of this product, tamper-resistant bait stations must have the following characteristics:

- * constructed of high-strength material (e.g. metal or injection moulded plastic) and resistant to destruction by children and non-target animals;
- * entrance designed so that children and non-target animals cannot reach the bait;
- * internal structure that prevents bait from being shaken loose;
- * access panel which fastens securely and locks (e.g. metal screw or padlock);
- * capable of being securely fastened to a surface (e.g. nailed down); and
- * clearly labelled: "WARNING POISON".

- The **USE LIMITATIONS** section of the product labels, with the exception of those products that consist of meal, treated whole-grain and pelleted forms of bait, must be amended to include:

The bait stations used in locations where children may be exposed must meet the standards for ability to isolate bait from children (i.e. tier 1, 2 or 3 bait station). Please refer to PMRA Information Note *Requirements for Bait Stations Used for the Placement of Rodenticide Bait*, available at healthcanada.gc.ca/pmra, for more information.

[Please note that this Information Note is published as a draft in Appendix VI.]

- The **USE LIMITATIONS** section of the label of commercial class, concentrated products (to be diluted into solid or liquid bait), must be amended to include:

For indoor use only. Do not use in areas accessible to children, pets and non-target wildlife.

Do not use in homes or other residential settings.

and to delete any residential sites.

Commercial class end-use product labels of products containing warfarin, bromadiolone, diphacinone, zinc phosphide, chlorophacinone or bromethalin must be modified as follows:

- The **USE LIMITATIONS** section of the product labels, with the exception of those products that consist of meal, treated whole-grain and pelleted forms of bait, must be amended to include:

Bait **MUST** be placed in bait stations for all outdoor, above-ground placements. **Tamper-resistant** bait stations that meet the standards for ability to isolate bait from children and dogs, and for weather resistance (i.e. tier 1 bait station) must be used in locations accessible to children, pets and non-target wildlife. Please refer to PMRA Information Note *Requirements for Bait stations Used for the Placement of Rodenticide Bait*, available at healthcanada.gc.ca/pmra, for more information.

[Please note this Information Note is published as a draft in Appendix VI.]

The labels of commercial class products containing difethialone must be amended to include:

For indoor use only.

The labels of commercial class products containing warfarin, bromadiolone, diphacinone, zinc phosphide, chlorophacinone or bromethalin that currently allow rat and mouse baits to be placed "in and around buildings", "indoors and against the outside walls of buildings" or "inside and in areas adjacent to buildings" must be amended to read:

Indoors and outdoors against the outside walls of buildings.

This restriction applies to placing rat and mouse baits around residential, commercial, agricultural (e.g. feed barns, storage sheds, poultry houses), industrial and public buildings as well as closed structures, including garbage dumpsters and transport/cargo vehicles. This restriction does not apply to other outdoor uses, including rangeland, fields, nurseries, orchards, shelter belts, plantations and cropland.

Appendix VI Requirements for Bait Stations Used for the Placement of Commercial Class Rodenticide Bait Products

In Re-evaluation Note REV2009-05, *Proposed Risk Mitigation Measures for Eight Rodenticides*, the PMRA proposed additional risk mitigation measures and updated the requirements concerning the bait stations used for commercial class rodenticide products containing warfarin, chlorophacinone, diphacinone, brodifacoum, bromadiolone, difethialone, bromethalin or zinc phosphide. This document also states it is the responsibility of the users of commercial class products to obtain or construct bait stations that are appropriate for the use situation (i.e. resistant to weather and/or to tampering by children and dogs) and consistent with label requirements.

This Information Note provides additional information on the PMRA's proposed requirement for bait stations to the users of commercial class products.

Bait Stations Characteristics

The bait stations used for the placement of rodenticide baits must have specific characteristics, depending on the use situation.

Outdoor Use in Locations Children, Pets and Non-target Wildlife Can Access

Tier 1 bait stations must be used outdoors in locations accessible to children, pets and non-target wildlife when placing rodenticide baits above ground. They must be weather resistant and resistant to tampering by children and dogs. As such, they must have the following characteristics:

- be constructed of high-strength material (e.g. metal or injection moulded plastic) and resistant to destruction by children and non-target animals;
- be resistant to destruction or weakening by elements of typical non-catastrophic weather (i.e. snow, rain, extremes of temperature and humidity, direct sunshine, etc.);
- have an entrance designed so that children and non-target animals cannot reach the bait;
- have an internal structure that prevents bait from being shaken loose;
- have an access panel that fastens securely and locks (e.g. metal screw or padlock); and
- be clearly labelled: "WARNING POISON".

Indoor Use in Locations Pets or Livestock Can Access

Tier 2 bait stations must be used outdoors in locations accessible to pets or livestock. They must be resistant to tampering by children and dogs. As such, they must have the following characteristics:

- be constructed of high-strength material (e.g. metal or injection moulded plastic) and resistant to destruction by children and non-target animals;
- have an entrance designed so that children and non-target animals cannot reach the bait;
- have an internal structure that prevents bait from being shaken loose;
- access panel that fastens securely and locks (e.g. metal screw or padlock); and
- be clearly labelled: "WARNING POISON".

Indoor Use in Locations Pets or Livestock Cannot Access

Tier 3 bait stations are required for placing rodenticide bait in locations not accessible to pets or livestock. They must be resistant to tampering by children. As such, they must have the following characteristics:

- be constructed of high-strength material (e.g. metal or injection moulded plastic) and resistant to destruction by children;
- have an entrance designed so that children cannot reach the bait;
- have an internal structure that prevents bait from being shaken loose;
- have an access panel that fastens securely and locks (e.g. metal screw or padlock); and
- be clearly labelled: "WARNING POISON".